

REMARKS

Claims 1-61 are pending. Claims 31-34, 37, 38, 44-46, 49, 50, 54-58, and 61 are under examination.

Rejection Under 35 U.S.C. § 101

The rejection of claims 31-38, 43-46, 49, 50, 54-58 and 61 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter is respectfully traversed. Applicant respectfully submits that the claimed methods are directed to statutory subject matter.

The claims are directed to a method for determining a nuclear packing efficiency (NPE) for a cell or population of cells, and includes the steps of “measuring a biochemical component (BC) of the nucleus of a cell” and “measuring a spatial displacement of the nucleus (SDN) of the cell.” The fact that some aspects of the claimed method “can be carried out on a computer” does not change the claim from a statutory method to a non-statutory “abstract idea, law of nature or natural phenomenon.” As described in the specification, the methods of the claimed invention, which allow for a determination of the efficiency of nuclear packing, which is a characteristic of the nucleus and a useful indication of the condition of the cell as a whole.

Claim 31 recites in step (a)(1) “measuring a biochemical component (BC) of the nucleus of a cell” and in step (a)(2) “measuring a spatial displacement of the nucleus (SDN) of the cell.” Such a measurement cannot be made without a cell. The fact that a measurement of a biochemical component or the spatial displacement of the nucleus of a cell can be made and subsequently stored on a computer does not change the fact that the measurement was made and certainly does not convert a statutory method claim to a non-statutory “abstract idea, law of nature or natural phenomenon.” Accordingly, Applicant respectfully submits that the claims are directed to statutory subject matter, not to a judicial exception.

Moreover, the Office action incorrectly states that “tangible” requires outputting or displaying the result of the method. Current Office Action mailed July 14, 200, at page 4. The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. Rather, the tangible requirement requires that the claim must recite more than a § 101 judicial

exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real world result. Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972) (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a . . . process may well be deserving of patent protection.” Diamond v. Diehr, 450 U.S. 175, 187 (1981). In other words, the opposite meaning of “tangible” is “abstract.” As described in the specification, the methods of the claimed invention, which allow for a determination of the efficiency of nuclear packing, which is a characteristic of the nucleus and a useful indication of the condition of the cell as a whole. As such, this measurement represents a tangible, real life benefit to the user, not an abstract idea.

Applicant respectfully submits that the claimed methods are directed to statutory subject matter. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 56 and 58 under 35 U.S.C. § 112, second paragraph as allegedly indefinite is respectfully traversed. Applicant respectfully submits that the claims are clear and definite.

The Court of Appeals for the Federal Circuit has held and repeatedly affirmed that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure).

The Examiner argues that the meaning of the term “range” is unclear with regard to the metes and bounds of the term. Current Office Action mailed July 14, 2007, at page 6. Applicant

respectfully directs the Examiner's attention to the following excerpt of the originally filed specification, which further clarifies the term "range" in the context of the claimed invention:

NPEs and NPE contours can be used to identify cells having a phenotype of interest. Cells can be identified by comparing their NPEs with other NPEs. For example, an NPE of a cell of interest can be compared with a predefined range of NPEs for a reference population of cells, or against other cells in the sample. As a result, NPEs and NPE contours are a useful characteristic to identify the phenotype of cells in a sample.

Specification, page 20, lines 14-22.

Applicant submits that, when viewed in light of the specification of which they are part, claims 56 and 58 are sufficiently clear and definite to the skilled person to comply with the second paragraph of section 112 of the Code. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 102

The rejection of claims 31, 37, 38, 44-46, 49, 50 and 54-58 under 35 U.S.C. § 102(b) as allegedly anticipated by Irinopoulou et al., Anal. Quant. Cytol. Histol. 20:351-357 (1998), is respectfully traversed. Applicant respectfully submits that the claims are novel over Irinopoulou et al.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

Irinopoulou et al., appears to describe the indirect measurement of nuclear volume by using a surrogate for nuclear volume, the staining of DNA. Such a measurement reflects the volume of the DNA, but not the volume of the nucleus, despite the assertion in Irinopoulou et al. that it is a measurement of nuclear volume. Irinopoulou et al. provides *no teaching or suggestion* of the recited methods for determining nuclear packing efficiency (NPE) of a cell or population

of cells that recite measuring a spatial displacement of the nucleus (SDN) of the cell. The use of three-dimensional volume measurements on one biochemical component of the nucleus in combination with DNA content as used by Irinopoulou et al. is distinct from the claimed methods directed to measurement of NPE. The Examiner, in rebuttal, directs Applicant's attention to Irinopoulou et al., at page 355, Figure 3, and col.1:17-19, and asserts that the excerpt teaches measurement of nuclear volume. Current Office Action mailed July 14, 2007, at p. 9. As explained herein and previously on the record, regardless of the assertion by Irinopoulou et al. that a measurement is provided of nuclear volume, no such measurement is provided by the cited reference. Applicant respectfully submits that the claimed methods are novel over Irinopoulou et al. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 103

The rejection of claims 31, 37, 38, 44-46, 49, 50, 54-58 and 61 under 35 U.S.C. § 103 as allegedly obvious over Irinopoulou et al., *supra*, and further in view of Baldetorp et al., Cytometry 13:577-585 (1992), is respectfully traversed. Applicant respectfully submits that the claimed methods are unobvious over Irinopoulou et al., alone or in combination with Baldetorp et al.

As discussed above, Irinopoulou et al., at best, describes the indirect measurement of nuclear volume by using a surrogate for nuclear volume, the staining of DNA. Such a measurement reflects the volume of the DNA but not the volume of the nucleus, despite the assertion in Irinopoulou et al. that it is a measurement of nuclear volume. Baldetorp et al. does nothing to cure the deficiencies of Irinopoulou et al. Baldetorp et al., at best, describes measurement of DNA ploidy using image cytometry of human breast cancer but provides no teaching or suggestion of the claimed methods, which measure spatial displacement of the nucleus (SDN). The combination of Irinopoulou et al. and Baldetorp et al. thus the prior art references fails to teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Absent such a teaching or suggestion, Irinopoulou et al., alone or in combination with Baldetorp et al., cannot render the claimed methods obvious.

Applicant respectfully submits that the claimed methods are unobvious over Irinopoulou et al., alone or in combination with Baldetorp et al. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Double Patenting

The rejection of claims 31-34 for obviousness-type double patenting over claims 6 and 21-23 of U.S. Patent No. 6,587,792, is respectfully traversed. Applicant respectfully requests that this rejection be held in abeyance until there is an indication of allowable subject matter.

In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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